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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,504	07/25/2003	Clark C. Davis	1001.1869101	1503
28075 7590 10/29/2007 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			EXAMINER SZMAL, BRIAN SCOTT	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 10/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.		Applicant(s)	
	10/604,504		DAVIS ET AL.	
	Examiner		Art Unit	
	Brian Szmal		3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 25, 27, 53-59, 78 and 81-87 is/are pending in the application.
- 4a) Of the above claim(s) 5, 9, 11, 12, 15-17, 21, 54, 56 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 10, 13, 14, 18-20, 25, 27, 53, 55, 58, 59, 78 and 81-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2007 and 16 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/8/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 8, 2007 has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4, 6-8, 10, 14, 19, 20, 25, 27, 53, 55, 58, 59, 78 and 81-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) in view of Shiber (5,135,531), as evidenced by Hernandez et al (5,396,212).

Jacobsen et al disclose a coronary guidewire system and further disclose an elongate body having a proximal end, a distal end and a longitudinal axis extending at least from the proximal end to the distal end; a helical coil formed of radiopaque wire (see Figures 15-17; Column 11, lines 66-67; and Column 12, lines 1-5); the body comprising a tubular member (514) having a plurality of slots configured to make the tubular member (514) more flexible in bending; the first coil located at or near the distal

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end, the first coil substantially comprising a substantially radiopaque material (see Figures 15-17; Column 11, lines 66-67; and Column 12, lines 1-11); a core wire (501), at least part of the core wire being located inside the tubular member (514), at least a portion of the core wire (501) being located inside the first coil (see Figures 15-17); the medical device is a guidewire (see Column 2, lines 39-42); the core wire (501) being attached with a joint to the first tubular member (514) at least at the proximal end, the joint comprising a first coil circumscribing the core wire (501), the first coil being at least partially inside the first tubular member (514), and the joint comprises at least one of solder and adhesive (see Column 12, lines 9-34); the core wire (501) being metal and the first coil is metal, the joint comprising solder attaching the first coil to the core wire (501) and adhesive attaching at least one of the first coil, the core wire and the solder to the first tubular member (514) (see Column 12, lines 9-34); the tubular member (514) comprising a plurality of slots formed in the tubular member, at least a plurality of slots being substantially perpendicular to the axis, the slots being formed in a plurality of groups, and at least a plurality of groups comprising a plurality of slots at substantially the same location along the axis (see Figure 18); the core wire (501) having a tapered portion, the joint being located at least partially within the tapered portion (see Figures 14 and 18); the core wire (501) further being attached to the first tubular member (514) at the distal end of the tubular member (514) (SEE Column 12, lines 9-34); the core wire (501) further being attached to the tubular member (514) at least one location intermediate (518) the proximal end and the distal end (see Column 12, lines 9-11); the core wire (501) comprising an abrupt change in diameter between the proximal end and

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the distal end (see Figure 14); radiopaque material inside the tubular member (514), at or adjacent to the distal end of the tubular member (514) (see Figure 18; Column 11, lines 66-67; and Column 12, lines 1-11); the core wire (501) being attached to the tubular member (514) at the distal tip (520) of the core wire (501); and the core wire (501) having at least one abrupt change in cross-sectional dimension, the abrupt change being at or adjacent to the joint (see Figures 14-18).

Jacobsen et al, however fail to disclose the coil being formed from a wire having a substantially non-circular cross section, the cross section having a greater dimension in the radial direction than in the axial direction, wherein prior to winding, the wire has two substantially flat opposite non-parallel sides that are out of parallel by an angle, and after winding into the coil, the sides are substantially parallel.

Shiber discloses a guided atherectomy system and further discloses the coil being formed from a wire having a substantially non-circular cross section, the cross section having a greater dimension in the radial direction than in the axial direction, and after winding into the coil, the sides are substantially parallel. See Figure 11; and Column 6, lines 45-56.

One of ordinary skill in the art would recognize Shiber implicitly teaches a coil that is created from a trapezoidal cross-sectioned wire and when the coil is formed, the trapezoidal shape becomes a rectangular cross section. In order to obtain the rectangular cross section as taught by Shiber, the wire would have to initially be of a trapezoidal shape before being formed into the coil, because if the wire was initially of a rectangular cross section, the formed coil would be formed into a trapezoidal cross

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section due to the increase of material on the inside of the formed coil. Hernandez et al discloses a means for winding transformer wire and further discloses the fact that a wire having a rectangular cross-section prior to bending about a radius would become a wire with a trapezoidal cross-section after bending about a radius. See Column 2, lines 53-63 of Hernandez et al. Therefore, Shiber implicitly discloses the use of a trapezoidal shaped flat stock prior to winding into a coil to form the shown rectangular cross-section.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guidewire coil of Jacobsen et al to include the use of a non-circular cross section, as per the teachings of Shiber, since the substitution of a non-circular cross-section coil in the place of a circular cross-section coil would provide the predictable result of being able to navigate a guidewire through the vasculature of the patient.

3. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) and Shiber (5,135,531), as evidenced by Hernandez et al (5,396,212) as applied to claim 7 above, and further in view of Lui (2002/0010475 A1).

Jacobsen et al and Shiber, as discussed above, disclose a guidewire means but fail to disclose the coil formed from wire having a thickness, the first coil having at least a portion of its length with a pitch of at least 1.5 times the wire thickness.

Lui discloses a means for removing an implanted lead from tissue and further discloses the coil formed from wire having a thickness, the first coil having at least a

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portion of its length with a pitch of at least 1.5 times the wire thickness. See Paragraph 0126.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pitch of the coil of Jacobsen et al and Shiber to be at least 1.5 times the wire thickness, as per the teachings of Lui, since it is well known in the art to utilize certain pitches within the coil to obtain a required flexibility.

4. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) and Shiber (5,135,531), as evidenced by Hernandez et al (5,396,212) as applied to claim 7 above, and further in view of Levine et al (2003/0009157 A1).

Jacobsen et al and Shiber, as discussed above, disclose a guidewire means, but fail to disclose the tubular member having a chamfer at the proximal end.

Levine et al disclose a flexible flow apparatus and further disclose the tubular member having a chamfer at the proximal end. See Paragraph 0153.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Jacobsen et al and Shiber to include the tube having a chamfer at the proximal end, as per the teachings of Levine et al, since it would provide a means of securing the tube to the core and coil.

Response to Arguments

5. Applicant's arguments filed October 8, 2008 have been fully considered but they are not persuasive.

The Applicants argue that neither Jacobsen et al nor Shiber teach the edge winding of a flat stock having two surfaces out of parallel by an angle into a coil having parallel surfaces. Shiber clearly discloses the end product of a coil having parallel surfaces. Based on the evidence of Hernandez et al as discussed above where a flat stock is rectangular in shape prior to winding, then becoming trapezoidal in shape with more matter in the inside radius of the curve after winding, one of ordinary skill in the art would have to utilize a flat stock having a trapezoidal shape prior to winding in order to obtain a rectangular cross section (as shown by Shiber) after winding into a coil. Based on the provided evidence of Hernandez et al, Shiber does implicitly disclose the claimed process for forming a coil into a rectangular-shaped cross-section.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Jacobsen et al teaches the use of at least one type of "coil" at the distal end of the guidewire, while Shiber teaches the use of a coil having a rectangular cross-section. One of ordinary skill in the art would have been able to substitute the coil of Shiber with the coil of Jacobsen et al to obtain a guidewire capable of traversing the vasculature of the patient.

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Furthermore, based on the Applicants' argument that there is no specific suggestion or teaching in the references of Jacobsen et al and Shiber to combine the references in order to modify the coil of Jacobsen et al, the recent KSR decision forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See *Ex Parte Smith*, USPQ2d, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007)(citing KSR, 82 USPQ2d at 1396).

With regards to Claim 25, the Applicants argue that Jacobsen et al fail to teach the limitation of the core wire comprising a section that has an abrupt change in cross sectional dimension between the proximal end and the distal end. The Examiner would like to point out in Figure 14, section 506 provides a proximal portion that is nearly twice as thick as the distal portion of section 506.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who's telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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